filed with the primary purpose of delaying generic approval if the petition does not also raise valid scientific or regulatory issues.[48] As noted, the FDA had not used the provision even once through fiscal year 2014. It is certainly possible that a differently worded authority would prompt greater activity from the Agency, but one could argue that the FDA may not be the right fit for such a role. The FDA may be better suited to evaluate science-related bad behavior than competition-related bad behavior.

An alternative would be to provide greater power for competition authorities (such as the Federal Trade Commission (FTC) or the Department of Justice (DOJ)) or third-party actors (such as the competitors who suffer harm) to act against anti-competitive behavior involving citizen petitions. Antitrust actions, however, are slow and expensive.[49] Moreover, if the experience with pay-for-delay settlements is a guide, by the time the courts slowly begin choking off the behavior, pharmaceutical companies will have altered their tactics. Antitrust law simply may not be sufficiently nimble.

Most important, providing an effective antitrust pathway for challenging citizen petitions may require substantial shifts in doctrines related to antitrust and regulatory agencies. As described in Chapter 4, the *Noerr-Pennington* line of cases, dating back to the 1960s, establishes the general principle that one has the right to petition the government without fear of antitrust liability. Although antitrust liability may still attach if one's petition to the government is judged to be a "sham," the bar for establishing a sham petition, at the moment, is extremely high.[50]

Certain types of citizen petition actions could be even more difficult to attack under antitrust law. For example, if citizen petitions are used to prevent a generic hopeful from obtaining samples of the branded product – which the generic needs in order to demonstrate that its drug is bioequivalent – antitrust actors trying to challenge the behavior would also run up against *Trinko*.[51] In the *Trinko* opinion, the Supreme Court all but shut the door on antitrust actions that claim a party's competitor has improperly refused to sell to it. In general, competitors are not required to sell to each other, and as the Department of Justice has argued, refusals to deal or "forced sharing" rarely helps consumers in the long run.[52] Although providing

[48] *See* 21 U.S.C. §355(q)(1)(E) (2012).

[49] *See generally* Robin Feldman, *Ending Patent Exceptionalism and Structuring the Rule of Reason: The Supreme Court Opens the Door for Both*, 15 Minn. J.L. Sci. & Tech 61 (2014).

[50] For a detailed discussion of the history of the *Noerr-Pennington* doctrine and its operation in practice, see Robin Feldman, *Federalism, First Amendment & Patents: The Fraud Fallacy*, 17 Colum. Sci. & Tech. L. Rev. 30 (2015).

[51] *See Verizon Comm. Inc. v. Law Offices of Curtis V. Trinko LLP.*, 540 U.S. 398 (2004).

[52] *See* U.S. Dep't of Justice, *Competition and Monopoly: Single-Firm Conduct Under Section 2 of the Sherman Act*, Ch. 7, Unilateral, Unconditional Refusals to Deal with Rivals (2008), www.justice.gov/atr/competition-and-monopoly-single-firm-conduct-under-section-2-sherman-act-chapter-7; *see also* Geoffrey Manne, *Senator Lee's Prescription for Regulatory Failure in the Generic Drug Market*